

We claim:

1. A method for the detection of a renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

- 1) obtaining a urine sample from a mammalian subject;
- 2) contacting the urine sample with an antibody for a renal tubular cell injury biomarker, the biomarker comprising NGAL, to allow formation of a complex of the antibody and the biomarker; and
- 3) detecting the antibody-biomarker complex.

2. The method according to Claim 1 wherein a plurality of urine samples from the subject is obtained intermittently.

3. The method according to Claim 2 wherein the urine samples are obtained continuously.

4. The method according to Claim 1 wherein the step of detecting the antibody-biomarker complex comprises contacting the complex with a second antibody for detecting the biomarker.

5. The method according to Claim 1 wherein the mammalian subject is a human patient.

6. A method of monitoring the effectiveness of a treatment for a renal tubular cell injury, comprising the steps of:

- 1) providing a treatment to a mammalian subject experiencing a renal tubular cell injury;

- 2) obtaining at least one post-treatment urine sample from the subject; and
- 3) detecting for the presence of a biomarker for the renal tubular cell injury in the post-treatment urine sample.

7. The method according to Claim 6 wherein the biomarker comprises NGAL.

8. The method according to Claim 6, further comprising the step of obtaining one or more subsequent post-treatment urine samples, wherein the step of providing treatment is continued until the presence of the biomarker in the subsequent post-treatment urine samples is not detected.

9. The method according to Claim 6 wherein the step of detecting comprises the steps of:

- i) contacting the urine sample with a capture antibody for the biomarker to allow formation of a complex of the antibody and the biomarker; and
- ii) detecting the antibody-biomarker complex.

10. The method according to Claim 9 wherein the step of detecting the antibody-biomarker complex comprises the steps of:

- (1) separating any unbound material of the urine sample from the capture antibody-biomarker complex;
- (2) contacting the capture antibody-biomarker complex with a second antibody for detecting the biomarker, to allow formation of a complex between the biomarker and the second antibody;
- (3) separating any unbound second antibody from the biomarker-second antibody complex; and

(4) detecting the second antibody of the biomarker-second antibody complex.

11. The method according to Claim 10 wherein the step i) comprises the step of contacting the urine sample with a media having affixed thereto the first antibody.

12. A kit for use in detecting the presence of an immediate or early onset biomarker for a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, in the urinary fluid of a subject, comprising:

- 1) a means for acquiring a quantity of a urine sample;
- 2) a media having affixed thereto a capture antibody capable of complexing with a biomarker for a renal tubular cell injury, the biomarker comprising NGAL; and
- 3) an assay for the detection of a complex of the biomarker and the capture antibody.

13. The kit according to Claim 12 wherein the quantity of the urine sample is less than 1 ml, more typically less than 10 microliters.

14. The kit according to Claim 12 wherein the acquiring means comprises an implement comprising a surface, the surface comprising the media.

15. The kit according to Claim 12 wherein the acquiring means comprises a container for accepting the urine sample, wherein the urine-contacting surface of the container comprises the media.

16. The kit according to Claim 12 wherein the assay comprises an ELISA.

17. The kit according to Claim 12 wherein the acquiring means comprises an implement comprising a cassette containing the media.

18. The kit according to Claim 12 that is a point-of-care kit.

19. The point-of-care kit according to Claim 18 wherein the quantity of the urine sample is less than 1 ml, more typically less than 10 microliters.

20. The point-of-care kit according to Claim 19 wherein the acquiring means comprises an implement comprising a dip-stick, the dip-stick surface comprising the media.

21. The point-of-care kit according to Claim 19 wherein the assay comprises a colorimetric dip-stick assay.

22. A competitive enzyme linked immunosorbent assay (ELISA) kit for determining the status of a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, of a mammalian subject, comprising a first antibody specific to NGAL to detect its presence in a urine sample of the subject.

23. The ELISA kit according to Claim 22 wherein the urine sample can comprise a fluid amount of about 1 milliliter or less.

24. A method of identifying the extent of a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, caused by an event, comprising the steps of:

- 1) obtaining at least one urine sample from a mammalian subject;

2) detecting in the urine sample the presence of a biomarker for a renal tubular cell injury; and

3) determining the extent of the renal tubular cell injury based on the time for onset of the presence of the biomarker in the urine sample, relative to the time of the event.

25. The method according to Claim 24 wherein the biomarker comprises NGAL.

26. The method according to Claim 24 wherein the event is a surgical procedure.

27. The method according to Claim 24 wherein the event is diminished blood supply to the kidneys, impaired heart function, surgical procedures, patients in intensive care units, and the administration of pharmaceuticals, radiocontrast dyes, or other medicament substances to the subject.

28. A method for the detection of a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, in a mammal, comprising the steps of:

1) obtaining a urine sample comprising up to 1 milliliter of the first urine from a mammalian subject;

2) contacting the urine sample with an antibody for a biomarker for a renal tubular cell injury, to allow formation of a complex of the antibody and the biomarker; and

3) detecting the antibody-biomarker complex.

29. The method according to Claim 28 wherein the biomarker comprises NGAL.